

## **OMB Questions for the Office of Research and Development**

Examiner Rosenfield

OMB-FY2019ORD-0004 (Maintaining IRIS Quality)

**OMB Question #4:** *As it relates to the new “portfolio” approach to compartmentalize certain aspects of the full IRIS assessment process, how do you retain the “gold standard” status of the program? In other words, how do you keep the high information quality reputation of the full IRIS process with these smaller, more targeted-approach efforts?*

### **ORD Answer:**

The portfolio approach does not alter the standard of practice for IRIS assessments. It simply moves the assessments away from one-size-fits-all to fit for the intended decision context.

- IRIS will continue to be the top tier source of toxicity information provided for use by the EPA and other health agencies to inform national standards, identify clean-up levels at local sites, and set advisory levels. IRIS assessments inform decisions under the Clean Air Act, Safe Drinking Water Act, CERCLA/Superfund, and TSCA.
- IRIS will continue to use transparent and systematic processes with robust, independent peer review.
- For the NCEA portfolio approach, instead of one-size-fits all, assessments will be developed with a focus on scoping and problem formulation to define user needs and frame the scientific questions prior to draft development, and will continue to incorporate scientific and public input at the outset. The scale and strength of the scientific evidence will also inform the scoping and problem formulation.
  - As presented with the recent 3 IRIS assessment plans, chloroform is a smaller targeted assessment which will undergo the steps of the IRIS process and a letter peer review, likely within a 12- to 18-month period from start to finish. Ethylbenzene, on the other hand, will likely take close to 24 months to be developed and may be peer reviewed by an SAB panel, which generally has been taking an additional 12 months. Formaldehyde, on the other hand, will be peer reviewed by the NAS. All these assessments will meet the highest standard of assessment practice, regardless of size.
- Rapid response “emergency” assessments may also be conducted as part of NCEA’s portfolio approach. In these cases, a full systematic review may not be feasible, although the transparency tenants of systematic review could be implemented. For example, a description of the methods (e.g. expert input, use of existing assessment, use of read across analysis or modeled evidence) and expression of confidence in the evidence would be included in the rapid response.